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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/301,380 06/15/01 MURPHY

G 20093A-00210

020350 HM12/0828
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EXAMINER

SCHMIDT, M

ART UNIT

PAPER NUMBER

1635

13

DATE MAILED:

08/28/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.

09/301,380

Applicant(s)

MURPHY ET AL.

Examiner

Mary Schmidt

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claims 1-21 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

KATRINA TURNER
PATENT ANALYST

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 3-13, 16-17 and 19, drawn to pharmaceutical compositions comprising antisense, methods of treatment using antisense and kits comprising antisense or primers which hybridize to Nr-CAM, classifiable in classes 514 and 536, subclasses 44 and 24.5, respectively.
- II. Claims 1-10, 12-13, 16, and 18-19, drawn to pharmaceutical compositions comprising antibodies or analogs/derivatives which bind Nr-CAM, methods of treatment using antibodies and kits comprising antibodies to Nr-CAM, classifiable in class 514 and 530, subclasses 2 and 387.1, respectively .
- III. Claims 3-10, 12-13 and 19, drawn to methods of treatment with nucleic acids comprising a portion of the Nr-CAM gene into which a heterologous sequence has been inserted for the purposes of recombination in to the Nr-CAM gene, thus inhibiting the Nr-CAM gene, classifiable in class 514, subclass 44.
- IV. Claims 14-15 and 20-21, drawn to methods of diagnosing or screening for a disease, classifiable in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. Invention I is drawn to compositions and methods comprising antisense or primers which bind Nr-CAM. Invention II is drawn to compositions and methods comprising antibodies or analogs/derivatives which bind to Nr-CAM. The nucleic acids of Group I have physical and chemical structural differences from the antibodies, analogs or derivatives of Group II. As such, they operate differently to bind and inhibit the Nr-CAM.

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. Invention I is drawn to compositions and methods comprising antisense or primers which bind Nr-CAM. Invention III is drawn to methods of treatment with a nucleic acid that recombines with Nr-CAM thus inhibiting Nr-CAM. The nucleic acids of Group I differ in structure from the nucleic acids of Group III since antisense are the opposite from the sense strand of the target gene and thus act by binding the target and not by recombination with the sense strand of the target gene.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In

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the instant case the different inventions have different modes of operation. Invention II is drawn to compositions and methods comprising antibodies or analogs/derivatives which bind to Nr-CAM. Invention III is drawn to methods of treatment with a nucleic acid that recombines with Nr-CAM thus inhibiting Nr-CAM. The antibodies of Group II have different physical and chemical structures than the nucleic acids of Group III. As such, they operate differently to inhibit the Nr-CAM.

Inventions (I, II or III) and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. Inventions I-III are drawn to methods of treatment, pharmaceutical compositions and kits comprising the therapeutic agents. Invention IV is drawn to methods of screening and diagnosis of a disease. The method steps thus differ in their function.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, the search required for Groups I, II, III or IV is not required for the alternative Groups, and because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

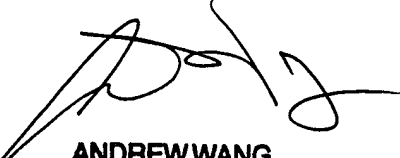
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary M. Schmidt whose telephone number is (703) 308-4471. The examiner can normally be reached on Monday-Friday 9:00 AM- 5:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 746-5264 for regular communications and (703) 746-5264 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3413.

August 14, 2001.



ANDREW WANG
PRIMARY EXAMINER